

REMARKS

Applicants wish to thank Examiner Brown and his supervisor, Examiner Housel, for meeting with applicants' representative and Dr. Natarajan Sethuraman. Applicants provide the following remarks in accordance with what was discussed during the interview.

Claims 1-23 and 31-46 are cancelled. Claims 24-30 and 47-57 are currently pending, with claims 24-30 and 47-50 withdrawn. Accordingly, claims 51-57 are currently presented for prosecution.

I. Obviousness-Type Double Patenting

With this response, applicants submit a terminal disclaimer that addresses U.S. patent No. 6,312,939, the "parent" of the present application. Thus, the subject rejection is obviated and should be withdrawn.

II. Claims 51-57 are Clear in Light of the Specification

Claims 51-57 stand rejected for indefiniteness under 35 U.S.C. § 112, second paragraph. As discussed during the interview, the phrase "therapeutically suitable glutaminase" is clearly described in the specification. In particular, on page 9 the specification states that "[g]lutaminase enzymes according to the present invention are therapeutically suitable if they display high enzyme activity at physiological pH, *i.e.*, between about pH 6.5 and 8.5." The enzyme activity of glutaminase is depletion of glutamine. *See* page 1 of the specification. Accordingly, applicants submit that the meaning of the phrase "therapeutically suitable glutaminase" in claim 51 is clear.

III. Claims 51-57 are Novel Over Ikura

Claims 51-57 stand rejected as anticipated by JP 01300889 ("Ikura"). According to the English abstract, Ikura discloses a method for manufacturing MTGase, otherwise known as "microbial transglutaminase." The Examiner asserted that Ikura's transglutaminase is a therapeutically suitable glutaminase, per claim 51, based on the understanding that "therapeutically suitable" means "immunologically compatible with the subject of the study."

As noted above, however, the specification defines a therapeutically suitable glutaminase, according to the claimed invention, as an enzyme that depletes glutamine, which MTGase does not do. Rather, transglutaminase catalyses the formation, in proteins, of an amide bond between side

chain glutamine and side chain lysine residues, with the concurrent elimination of ammonia. *See* Huang *et al.*, *J. Biochem.* 112: 229-34 (1992), stating that transglutaminase "catalyzes the formation of a 'zero length' covalent cross-link between glutamine and lysine residues in peptides..." (a copy of which is attached hereto as Appendix A). Accordingly, MTGase is *not* a therapeutically suitable glutaminase, and claims 51-57 are novel over Ikura.

Applicants respectfully request that, should he find that claims 51-57 are allowable, the Examiner also consider rejoinder of restricted claims, conditioned on their revision to conform to the allowable subject matter.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 CFR § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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